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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,824	07/25/2001	William C. Olson	62942-B/JPW/SHS	7125

7590 04/20/2004

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New York, NY 10036

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/912,824

**Applicant(s)**

OLSON ET AL.

**Examiner**

Jeffrey S. Parkin, Ph.D.

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,43 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,43 and 46-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Serial No.: 09/912,824

Applicants: Olson, W., and P. J. Maddon

Docket No.: 62942

Filing Date: 07/25/01

### Detailed Office Action

#### *Status of the Claims*

Acknowledgement is hereby made of receipt and entry of the amendment filed 02 January, 2004. Claims 1, 2, 43, and 46-48 are currently under examination.

#### *35 U.S.C. § 103(a)*

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 43, 46, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Lee et al. (1999) and Furuta et al. (1998). As previously set forth, Lee and colleagues (1999) provide monoclonal antibodies that bind to the HIV-1 chemokine coreceptor CCR5 and inhibit viral binding to said receptor. Furuta and associates (1998) provide a compound (DP-178/T20) that prevents Env-mediated membrane fusion by binding to a fusion intermediate. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine two known compounds that are capable of inhibiting viral replicative events into a single composition since this would provide a more efficient antiviral compound. One of ordinary skill in the art would have also been motivated to employ such a composition in inhibitory methodologies to prevent HIV-infection.

Applicants assert that the claimed invention is allowable because the combination of ingredients provides an unexpected and synergistic effect in terms of inhibiting HIV-1 infection. Applicants are reminded that the claims are simply directed toward a composition comprising two ingredients. The claims do not require any particular level of antiviral activity. While some specific combinations may provide synergistic effects (e.g., PRO 542 and T20), nevertheless, there is no requirement in the generic composition for such activity. The claims only require an admixture of two compounds. Both of the compounds are present in the prior art and known to display antiviral activity. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine two known compounds that are capable of inhibiting viral replicative events into a single composition since this would provide a more efficient antiviral compound. Applicants may wish to amend the claim language to incorporate the specific antiviral agents set forth in

the specification (i.e., A composition ... wherein the first compound is PRO 542 and the second compound is T-20 ...).

Claims 2, 43, 47, and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Lee et al. (1999) and Furuta et al. (1998), as applied supra to claims 1, 43, 46, and 48, and further in view of Valenzuela et al (1997). As previously set forth, Valenzuela and colleagues provide neutralizing monoclonal gp120-specific antibodies that block HIV-1 gp120 CD4-dependent and -independent binding. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine three known compounds that are capable of inhibiting viral replicative events into a single composition since this would provide a more efficient antiviral compound. One of ordinary skill in the art would have also been motivated to employ such a composition in inhibitory methodologies to prevent HIV-infection.

Applicants assert that the claimed invention is allowable because the combination of ingredients provides an unexpected and synergistic effect in terms of inhibiting HIV-1 infection. Applicants are reminded that the claims are simply directed toward a composition comprising three ingredients. The claims do not require any particular level of antiviral activity. While some specific combinations may provide synergistic effects (e.g., PRO 542, T-20, and PRO 140), nevertheless, there is no requirement in the generic composition for such activity. The claims only require an admixture of two compounds. Both of the compounds are present in the prior art and known to display antiviral activity. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine two known compounds that are capable of inhibiting viral replicative events into a single composition since this would

provide a more efficient antiviral compound. Applicants may wish to amend the claim language to incorporate the specific antiviral agents set forth in specification (i.e., A composition ... wherein the first compound is PRO 542, the second compound is T-20, and third compound is PRO 140 ...).

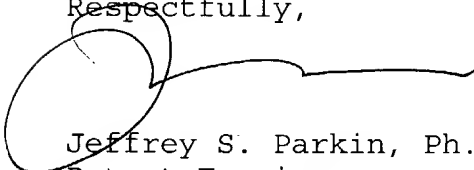
### **Correspondence**

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908.

The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

16 April, 2004